MULTI-MODAL STIMULATIONS TO MODIFY THE NEUROMOTOR RESPONSES OF HOSPITALIZED PRETERM INFANTS

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MULTI-MODAL STIMULATIONS TO MODIFY THE NEUROMOTOR RESPONCES OF HOSPITALIZED PRETERM INFANTS

SYNOPSIS SUBMITTED

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Abstract:

Purpose: The survival rate of preterm infants (PI) is drastically elevated by the modernization of the neonatal Intensive Care Unit (NICU) environment, Noxious sensory stimuli of (NICU) will adversely affect the neuronal organization of PI. This resulted in developmental impairment and motor issues, that have a greater influence on the later life of PI. Shreds of evidence state that, existing early interventions (EI) for the PI at high risk for developmental motor disorders are minimal and inconclusive. Hence, the study focusing on discovering effects of Multi-Modal Stimulations (MMS) including both sensory and motor interventions among the hemodynamically stable hospitalized PI is being drafted.

Method: The single-center, single-blinded pre-test post-test control group study design will consist of 56 PI admitted in the Level II and III NICU of a recognized tertiary care teaching hospital, will be recruited by convenient sampling method into two groups by the Zelen design. Group A (n=28) will receive MMS for five sessions for one week period along with regular lifesaving care and Group B (n=28) will receive only regular lifesaving care from NICU. Physiological status, anthropometric evaluation, and Infant Neurological International Battery (INFANIB) will be used as the outcome to analyze the neuromotor behavioral modifications among the hospitalized PI.

Results: The collected demographic and outcome measures will be assessed for their normality using the Shapiro-Wilk test. Within and between the group's comparison will be analyzed by paired t-test/Wilcoxon signed-rank test and unpaired t-test/Mann-Whitney U test respectively. Group and birth weight interaction on INFANIB will be determined by a two-way analysis of variance (ANOVA).

Conclusion: MMS trial, which includes both sensory and motor interventions, would be the first trial to the best of our knowledge, for modifying the neuromotor behavior of hospitalized P**I**.

1. INTRODUCTION

The Premature Infants (PI), may encounter numerous challenges for survival and maturation due to immature organelles as they were abruptly taken out from the mother's womb before the actual due. About 15 million neonates are estimated to be born with prematurity across the globe and India accounts for 3.5 million pre-mature birth out of 27 million newborns annually.[1,2] Over 70% of PI need hospitalization in a neonatal intensive care unit (NICU) and is necessary for the support and developmental maturation of babies born before term.[1,3]

Advanced medical technologies in the NICU results in improved survival rates among PI, although the persistence of long-term morbidities is common.[4] Daily they encounter many of the stressors in the NICU for their survival. The amount of these stressors are fluctuating with the respective health status of the individual PI and their response to the stressors. Such exposures result in structural and functional changes in specific brain areas, affecting the physical development, language, and social-emotional and adaptive behavior of the PI.[5,6] The PI has to adapt to an extrauterine environment with immature body systems which include neuromuscular, musculoskeletal, cardiovascular, pulmonary, and integumentary systems.[7] Approximately 50% of PI experience neurobehavioral impairments, including motor incoordination, cognitive impairment, attention deficits, or behavioral problems in later years of life. [8] An immature nervous system is not ready to process all the sensory information. In NICU, they are bombarded with sensory stimuli such as bright lights, loud noises, an intrusive environment, painful interventions, and unintentional and repeated disruption of sleep. These infants are at increased risk for sensory integration (SI) problems.[9]

Most of the PI experiences the atypical maturation of the brain and the sequence of maturation is based on extra-uterine sensory experience and atypical sensory stimuli in the NICU.[10] Noxious sensory inputs that PI experiences in the NICU negatively affect the neuronal organization, which is supposed to form during the final trimester of pregnancy.[9,11] The neonatal musculoskeletal system is fragile and vulnerable to injury. The PI have cartilaginous joints has a peak risk to develop osteopenia, 30-50% of them were reported with bone mineral deficiency.[9,12] Postulated that these painful and stressful treatments play a role in altering brain maturation and in negatively affecting the neurobehavioral outcomes of preterm infants.[13] and prolong stay in the NICU.

Healthy PI moves in greater ranges of motion and may never completely achieve the full flexion posture of a full-term newborn at the equivalent age, but limited hand to mouth activity due to limited flexor tone, altered sleep states, a lower activity state, and less cry.[14] The infant born with prematurity is vulnerable for the effect of gravity as they have immature muscle fibers and reduced flexor tone. The tone development in PI will take place in the quado-cephalic direction. This makes a PI achieve the hyper-extended posture. They also exhibit limited endurance and immature capacity to control more complex movements against the gravitational force.[9]

NICU is essential for the support and developmental maturation of neonates born before term.[3] With an increasing survival rates of preterm and low-birth-weight neonates, there is an increase in the number of these infants with motor impairments later in life, ranging from developmental coordination disorder to cerebral palsy (CP).[15] Myelination begins during the second trimester and is most rapid in the first year of life, and the process continues up to 30 years of age. It is, therefore,

important that neonates with motor dysfunction are identified early so that appropriate interventions can be implemented.[16]

1.1. Need of the study:

Evidence for the effectiveness of physiotherapy interventions are limited[9,17] and are inconclusive[18] for the infants, who are at high risk of developmental motor disorders and those who born prematurely. The persistent motor disability affects the child at its later age.[15] Early physiotherapy (PT) is expected to be fruitful in optimizing motor development of PI.[19]

1.2. Aim of the study:

To find the effect of multi-modal stimulation (MMS) including sensory and movement therapy among the stable Preterm Infants admitted to NICU/ward.

2. LITERATURE REVIEW

2.1. Physical therapy Interventions in the neonatal intensive care unit

The introduction of advanced tools in the NICU setup, significantly raised the survival rate of PI, [1,15] but the developmental impairment and motor issues are largely evident in the later phase of their life.[15] Early physiotherapy (PT) is expected to be fruitful in optimizing motor development of PI.[19]

2.1.2. Sensory Interventions:

The somatosensory system of humans continues to mature after birth.[17] Neurological immaturity in the PI is expressed by limitations in a variety of behaviors used to cope with sensory stimuli (SSt).[20] They are essential for the physiological and psychological development of infants. non-nutritive sucking (NNS) and tactile stimulation (TS) type of Supplementary SSt are proved their role in increasing the growth rate and the maturation of PI.[21]

The non-painful SSt can produce equal or higher levels of physiological stress activation than painful stimuli in term newborn and preterm neonates, both the newborn and the somewhat older ones. This stress activation may have both positive and negative effects on fragile PI.[17] Somatosensory stimulation (SSS) such as sucking and touch may influence the digestion, metabolism, and growth by activating the hormonal secretions from the gut and the Pituitary. The SSS also influences behavior. [21]

2.1.2.1. Tactile and kinaesthetic stimulation (TKS): The PI surviving beyond the postnatal period, major attention has been aimed towards growth and maturation. Along with the physiologic squeals of prematurity, the stressful neonatal intensive

care unit (NICU) environment and lack of TS may further compromise these vulnerable PI. [22] During intra-uterine (IU) life the TKS was provided through amniotic fluid, wall of the uterus, placenta, movement of baby inside the uterus as well as the movements of the mother. Amniotic fluid decrease as pregnancy reaches term due to increased fetus growth.[23] Due to prematurity PI lags with the TKS, that they would have experienced in the womb.[24] In the Postnatal period these PI, the IU environment can be controlled by the mechanical devices but the TKS was limited either due to minimal handling or by monotonicity of the NICU environment.[23] Massage is proved to be beneficial in combination with KS for daily weight gain in selected PI, but the length of hospital stay is not impacted by massage.[22] But a literature review on TKS suggests the shorter stay along with faster weight gain and better behavior.[25] It also facilitates the normal developmental rise in catecholamine excretion.[23,26] Thus TKS may be a much feasible way of promoting growth and behavioral organization even in very small PI.[27]

2.1.2.2. Multi-sensory stimulation (MSS): Multisensory stimulation (MSS) was viewed for its immediate beneficial effects on the neuromotor growth in PI at their term age.[28] ATVV (auditory, tactile, visual, and vestibular) procedures could be an integral part of the routine neonatal physiotherapy for healthy PN.

2.1.2. Hydrotherapy (HT)

The HT was proposed by Hippocrates in BC. It is proved to be safe and effective in reducing pain and improving sleep quality among PN admitted in NICUs. Apart from this HT Improves the muscle tone, enhance the audio-visual orientation, improves

feeding, contracture management, parental involvement can be achieved by HT and is extremely cost effective.[29]

2.1.3. Therapeutic Positioning (TP)

Positioning promotes self-soothing and self-regulation behavior, thus it is included in the personalized developmentally supportive care model, based on synactive theory.[30] It is one of the earliest neurodevelopmental interventions (NDI) in the NICU.[31] The infant born with prematurity is vulnerable to the effect of gravity as they have immature muscle fibers and reduced flexor tone.[9] Placing PI in prone or side-lying positions in the isolette or on a caregiver's chest has been shown to facilitate midline flexion and uncontrolled flailing, also stabilizes the vitals specially breathing.[32]

Lying in the side position may facilitate chin tuck and head control to achieve hand movements, play, and self-regulatory behavior of PI.[31] It also promotes midline movements,[30], and minimizes the gastroesophageal reflux disease (GERD).[33] TP in NICU promotes the head shaping of the PI.[34] Positioning can also be assisted by traditional swaddling or alternative positioning device or isolette.[31]

2.1.4. Physical activities **(PA)**

Mechanical forces stimulate bone formation and growth,[35] whereas Without the PA prolong NICU stay may cause the demineralization of bones, which further cease the maturation and growth of bone and promotes the deformities of the bone.[12,36] There may be a possibility to form contracture thus severely ill PI will be paralyzed for the recovery.[9]

2.1.4.1. Moyer-Mileur protocol (MMP): The PA program was based on the MMP, consisting of ten repetitions of each movement were performed on the wrists, elbows, shoulders, ankles, knees, and hips in the cephalocaudal direction, with an average of six movements per min, and was always performed by the same therapist, at least 30 min after being fed, five times per week for four weeks permitted significantly greater weight gain, length, Bone Mineral Density which could contribute to the prevention of osteopenia in prematurity. As the short-term effects of MMP were favorable and safe.[36]

2.1.4.2. Passive movements: Another Physiotherapy Protocol developed by Vignochi et al consists of Passive flexion and extension movements with soft articular compressions at the end of each movement. Ten repetitions on the wrists, elbows, shoulders, ankles, knees, and hips in the right and left lateral position was done for five days a week, for 15 minutes, performed at least 30minutes after the patient received food and till the infant reached 2000 g (hospital discharge). The study suggests the mitigation of bone resorption among the PI.[35]

3. METHODOLOGY

3.1. ***Study setting:*** Neonatal Intensive Care Unit of M. M. Super Speciality Hospital, Mullana Ambala district, Haryana-India

3.2. ***Study population:*** Preterm Infants (PI)

3.3. ***Sample size:*** 56

3.3.1. **Sample Size and Power:** Sample size for the study was calculated using the formula for comparing means with the level of significance as 0.05 (Zα = 1.96), with 90 % power (Zβ = 1.28) and 3.5 units change (d=3.5) in the primary outcome measure, INFANIB score as a clinically meaningful difference (CMD) with pooled standard deviations of, S = 3.2, from previous research.[28] In the study by, Kanagasabai et al,[28] the CMD of INFANIB was found to be, 3.08 against the proposed CMD of 2 by them. Hence, we have fixed the target to achieve a CMD of 3.3 between the groups. Thus making the required sample of 19.2 in each group. Considering a 20% drop-out rate (n=3.8), a final minimal required sample size of n=23. As the sample size cannot be considered in decimals, the value was rounded off to the next whole number) was estimated for each group of the study. This was further confirmed with G*Power ver. 3.1.9.4 software (Heinrich- Heine-Universität Düsseldorf, Düsseldorf, Germany; http://www.gpower.hhu.de/)[37] for the sample size calculations with Effect size (ES) = 0.98. (Control group = 59.16 ± 3.23; Study group = 62.24 ± 3.07; Effect size = Group difference / Pooled standard deviation; Effect size

= 62.24 – 59.16 / $(3.07)^2$ + $(3.23)^2$ / 2; Effect size = 3.08 / 3.15).[28] By substituting ES with the level of significance as 0.05 (α error prob), 0.90 (Power (1-β err prob) with 1:1 allocation ratio of a two-tailed test, we have estimated the sample size in each group has to be, n=23. By considering a 20% drop-out rate (n=4.6), we have obtained the final minimal required sample to be, n=28 (by the calculation, obtained minimal required sample size was, n= 27.6. As the sample size cannot be considered in decimals, the value was rounded off to the next whole number) in each group. Sample size estimation by both the methods (CMD and ES) to satisfy the traditional requirements considering CMD [28] and ES calculation proposed by Peacock et al.[37] So, the total sample size for the study will be, n = 56.

3.4. ***Ethical statement:*** The study protocol will be approved by the institutional research and ethics committee and the study will be done strictly following the guidelines of the Helsinki declaration, revised 2013.[38] After obtaining ethical approval from the institutional ethics committee, the study protocol will be uploaded in open access clinical trial registry platform, Clinical Trials Registry - India (http://ctri.nic.in/),[39] approved by WHO's International Clinical Trials Registry Platform (ICTRP) and International Committee of Medical Journal Editors (ICMJE),[40] with unique Universal Trial Number (UTN), U1111-1236-9478. Written informed consent will be taken from the participant's caregiver/parents before their enrolment in the study.

3.5. Selection criteria

Inclusion Criteria:	*Exclusion Criteria:*
• Infants born between 28 and 36 weeks of gestation • Birth weight ranging from 1,000–1500 g. • Medically stable PI	• Infants with congenital anomalies, congenital infections, and central nervous system injury

3.6. ***Recruitment and allocation:*** A total of 56 PI with LBW (PLBW) will be recruited by the **convenience** sampling to participate in this two-group pre-test post-test, single-blinded randomized clinical study. After the demographics, recruited PLBW will be randomly divided into two groups, experimental group, and control group with block randomization with randomized consent design (Zelen design). There will be four blocks, with the matrix design of 4X14 here 14 being rows. Each block contained 4 chits (2 chits for each group), totaling 56. Consent will be obtained only from the parent of PLBW were recruited in the experimental group. Those who will be allotted to the control group to receive the standard NICU care do not supply consent.[41] The subjects will be allotted to the group based on the randomly chosen chit by their parents. Once the block will be allotted, the next row block was opened. Thus, an equal number of PLBW will be assigned to each group over time. The experimental group will be receiving multimodal stimulations trial (MMS-trial): consisting of sensory and kinesthetic stimulations, and the Control Group(CG) will be receiving regular lifesaving hospital care. The experimental (MMS-trail) group will

receive the interventions for 1 weeks period, totaling 5 sessions. Each session will last for 30 minutes duration. The flow chart describing the details of the study is displayed in Figure-1.

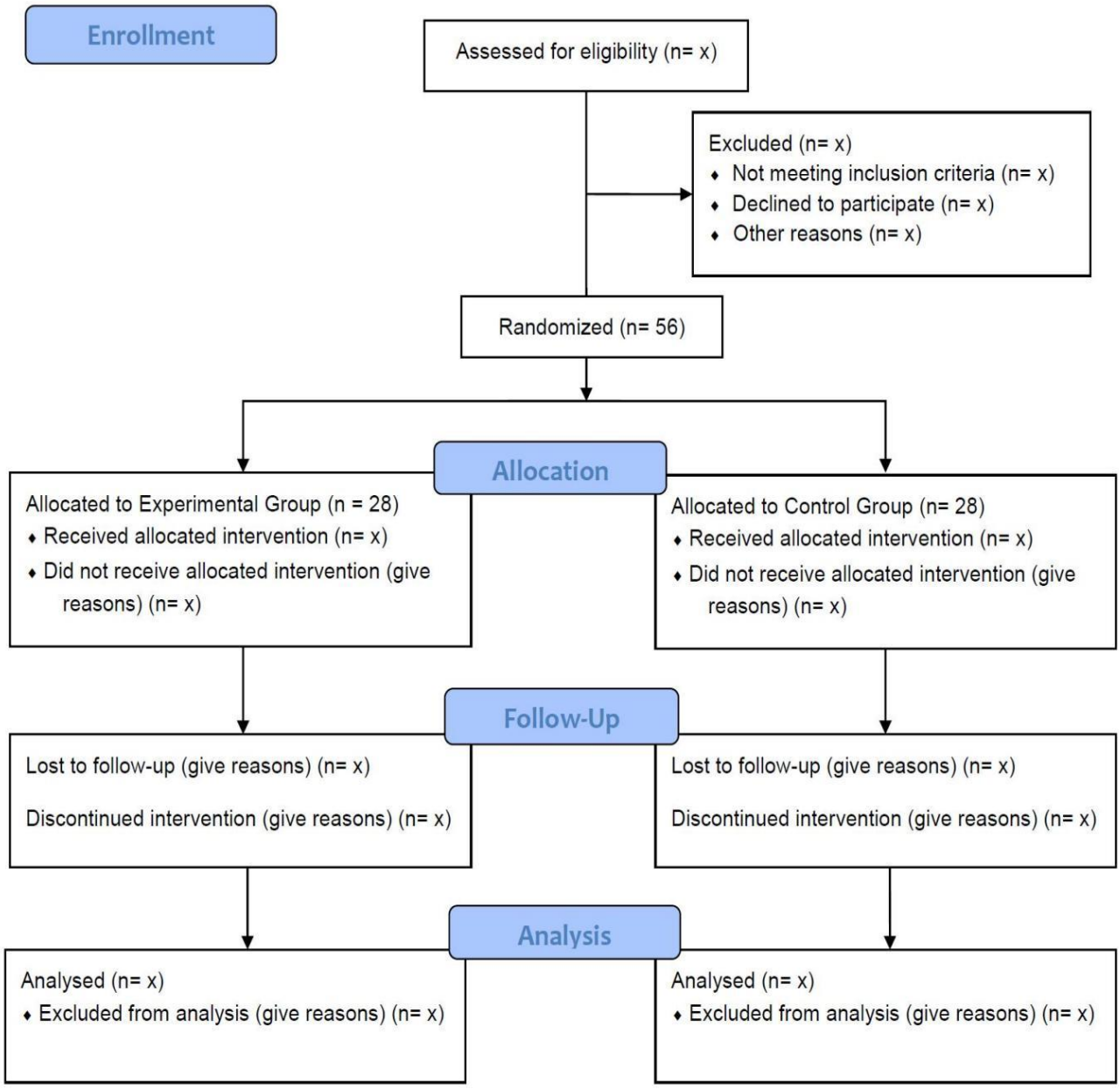
Enrollment
Assessed for eligibility (n= x)
Excluded (n= x)
Not meeting inclusion criteria (n= x)
Declined to participate (n= x)
Other reasons (n= x)
Randomized (n= 56)
Allocation
Allocated to Experimental Group (n = 28)
Received allocated intervention (n= x)
Did not receive allocated intervention (give reasons) (n= x)
Allocated to Control Group (n= 28)
Received allocated intervention (n= x)
Did not receive allocated intervention (give reasons) (n= x)
Follow-Up
Lost to follow-up (give reasons) (n= x)
Discontinued intervention (give reasons) (n= x)
Lost to follow-up (give reasons) (n= x)
Discontinued intervention (give reasons) (n= x)
Analysis
Analysed (n= x)
Excluded from analysis (give reasons) (n= x)
Analysed (n= x)
Excluded from analysis (give reasons) (n= x)

Fig: 3.1. flow chart describing the details of the study

3.7. *Interventions*

3.7.1. Control group (CG)

The CG will be receiving routine care from the nursing team as well as daily maternal care, such as being held in the mother's arms.[36,43]

3.7.2. Experimental group (MMS-trail group)

3.7.2.1. Sensory stimulations[28,44,45]

i. **Auditory Stimulation** will be in the form of a Soft lullaby between (30–40 dB) provided through a miniature speaker for 3 minutes.

ii. **Tactile Stimulation** will be provided through Gentle stroking massage, in a sequence of the chest, upper limbs, and lower limbs in the supine position for 3 minutes

iii. **Visual Stimulations** will be provided by suspending the Black and white visual stimulation cards at a distance of 8–10 inches from the PI for 3 minutes.

iv. **Vestibular Stimulation** will be provided through gentle horizontal and vertical rocking for 3minutes.

3.7.2.2. Movement therapy

i. **Passive Movements** will be guided Flexion-extension movements of the upper limb (wrist, elbow, and shoulder joints of both sides) and lower limb (bicycle riding pattern, Hand should be placed around knee joint) with articular compression. Care must be taken as PI consist of the cartilaginous joints at the wrist and ankle.[36]

ii. **Antigravity movements in prone** will be by positioning the PI in prone firmly at one or both sides of the trunk, distracting the infant's lower ribs down toward the pelvis and assisting caudal-ward weight transfer for 3 min

iii. **Antigravity movements in sitting(supported)** will be provided by lift the PI from supine or prone into sitting relatively vertical while providing trunk to pelvic alignment and stability as well as to pause during the movement and wait for 3 min

During the intervention program, physiological stress (PS) signs will be observed using the multi-parameter monitor. The heart rate (HR) greater than 200 or less than100 beats per minute, respiratory rate (RR) greater than 20 over baseline, and oxygen saturation (SpO2) below 86 % for more than 15 seconds define the PS.[46] The behavioral stress sign includes startle, tremors, yawning, finger splay, tone changes, state changes, gaze aversion, cry, hiccups, and tongue protrusion.[47,48] The intervention was modified (particular stimulation paused for 15 s and resumed if parameters recovered) based on the PI's physiological and behavioral stress responses to prevent overloading of the inputs.

3.7.3. Baseline assessment:

i. Gestational Age (weeks)
ii. Weight (gram)
iii. Length (centimeters)
iv. Head circumference ((centimeters)
v. Apgar score

3.7.4. Outcome measure: Infant Neurological International Battery (INFANIB)

INFANIB will be used as the primary outcome measure to assess the neuromotor development of the PN at term age (between 38 and 40 weeks of corrected gestational age). INFANIB is a valid and reliable outcome measure that consists of 20 items to assess the infant's motor development in supine, prone, standing, and suspended positions for reflexes and French angles as well as muscle tone and body posture.[49] INFANIB is simple and consumes less time, [50,51] and it will be used as the primary outcome measure to assess the neuromotor development of the neonate using corrected gestational age. INFANIB has excellent reliability of, ICC = 0.9 with 90% sensitivity and 83% specificity and acceptable predictive validity, in detecting developmental delay.[50,52] It could successfully detect the short-term effects of multisensory interventions on the neuromotor development of PN.[28] INFANIB consists of a total of 20 items to be evaluated in five positions, supine, prone, sitting, standing, and suspended.[51] Among them only 14 items; supine position (10 items) - hands closed/open, scarf sign, heel to ear, popliteal angle, leg abduction, dorsiflexion of the foot, foot grasp, tonic labyrinthine, asymmetric tonic neck reflex and pull to sitting; prone position (2 items) – all fours and tonic labyrinthine; sitting position (1 item) – sitting and standing position (1 item) – weight-bearing. Thus, the only total score of 70 will be considered instead of 100. PI will be considered abnormal if the cut-off point's ≤ 48. Pre-post MMS intervention changes of INFANIB will be considered for the data analysis.

3.8. **Data analysis:** The qualitative variables (nominal and ordinal scales) of the demographic dimensions collected, such as type of delivery will be reported in frequency rounded off to one decimal with percentages. In the case of, the quantitative variables (interval and ratio scales) of the demographic and outcome measures, to what extent the data match the normal distribution, could be confirmed by, “goodness of fit” test, Shapiro-Wilk (SW) test.[53] Hence, the SW test will be applied to assess for their normality, as the sample size of an individual group is less than 50 ($n < 50$).[54–56] The normality test can be sub-classified into descriptive statistics and theory-driven methods which use, both graphical and numerical methods.[55,57] The normality will be verified by numerical methods, skewness, and kurtosis for descriptive statistics and SW test for the theory-driven method. If skewness approaches zero, “0” and kurtosis approaches three, “3”, then according to the descriptive statistics method, the data will be considered normal.[57] Similarly, if the SW test is not significant ($p > 0.05$), then the distribution will be considered normal.[53] The descriptive statistics of the normally distributed data will be expressed in mean ± standard deviation. A paired t-test will be adopted to find out the differences between the experimental group and control group for pre-post intervention changes. While independent t-test will be used to compare the changes in mean values of the outcome measures between the MMS-trial group and control group at baseline and end of the 5^{th}-day intervention. If the data does not follow a normal distribution, then the descriptive statistics will be reported in mean with 95% confidence interval (CI) and range. Wilcoxon signed-rank test will be adopted to find out the differences between the experimental group and control group for pre-post intervention changes. While Mann-Whitney U test will be used to

compare the changes in mean values of the outcome measures between the experimental group and control group at baseline and end of the 5th-day intervention. To see the interaction between two independent variables, birth weight or type of delivery and treatment effect on the dependent variable, and INFANIB by 2 X 2-factor design will be reported using two-way analysis of variance (two-way ANOVA).[58] Here, two-way ANOVA will be executed between birth weight (Factor A) with two levels (NBW / AGA or LBW or SGA), or type of delivery (Factor A) with two levels (NVD or LSCS) and treatment group (Factor B) with two levels (MMS trial or control). If the data deviate from a normal distribution, a non-parametric form of two-way ANOVA known as, Friedman's two-way ANOVA, which is purely a hypothesis test will be used.[59] All the data will be analyzed using statistical software, statistical package for social science (SPSS), IBM SPSS version 20.0 (Armonk, NY: IBM Corp.). For all the analyses, a p-value < 0.05 was considered to be statistically significant.

4. **DISCUSSION:**

The long-term developmental sequelae associated with prematurity can include developmental delay in acquisition of age-appropriate motor skills and it may be precipitated by the noxious stimuli within the NICU.[60–63] The maturing PI brain is highly sensitive and changes rapidly, thus they required EI and a pleasant environment of NICU.[62] The EI is an umbrella term describing the variety of multi-disciplinary care delivered to children up to five years of age.[64,65] There are various physical therapy interventions namely positioning,[66] hydrotherapy,[29,67] motor physical therapies, tactile or massage, vestibular stimulation, sensory interventions, which were tested independently for their effects on neuromotor outcomes of PI. Whereas the effects of early Interventions like multisensory approach and tactile-kinesthetic stimulations were evaluated in combination.[68,69] The current study describes the MMS trial which is a unique customized early intervention trial to promote sensory and motor maturation among the PI. The effects MMS trial will be studied systematically by utilizing a standard randomized controlled trial where the control group has no intervention except standard medical and maternal care, which will not alter the effect size of successful interventions being tested.[62]

Like other reported trials our study also might minimize parental stress, improve quality of life, lead to early discharge from the NICU, and other hidden benefits to PN and their families.[70]

5. Conclusion:

MMS trial, which includes both sensory and motor interventions, would be the first trial to the best of our knowledge, for modifying the neuromotor behavior of hospitalized PI. The clinical effects of the MMS trial could be revolutionary in the treatment of developmental impairments during the later life of PI.

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Annexure –I: Informed Consent Form (English)

Informed Consent Form for the parents of preterm infants admitted in neonatal intensive care unit participating in the research "MULTI-MODAL STIMULATIONS TO MODIFY THE NEUROMOTOR BEHAVIOUR OF HOSPITALIZED PRETERM NEONATES"

Name of Principle Investigator : VENCITA PRIYANKA ARANHA, PT

Name of Organization : MAHARISHI MARKANDESHWAR DEEMED TO BE UNIVERSITY, MULLANA -AMBALA, HARYANA

Name of Supervisor : DR. AKSH CHAHAL. PT, PhD

Name of Co Supervisor : COL. DR. A.K. BHARDWAJ, MD (Paediatric)

Name of Project : MULTI-MODAL STIMULATIONS TO MODIFY THE NEUROMOTOR BEHAVIOUR OF HOSPITALIZED PRETERM NEONATES

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you agree that your child may participate)

Part I: Information Sheet

I am MRS. VENCITA PRIYANKA ARANHA and I work at *Maharishi Markandeshwar Deemed To Be University, Mullana - Ambala, Haryana,* doing some research which might help in the neuromotar maturation of your preterm neonate (PN). In our research we will assess many PN including both girls and boys, for their

physiological status and neuromotar maturation by using Infant Neurological International Battery (INFANIB). Whenever researchers study PN, we talk to the parents and ask them for their permission. After you have heard more about the study, and if you agree, before I can begin.

You do not have to decide today whether or not you agree to have your child participate in this research. Before you decide, you can talk to anyone you feel comfortable with. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose: To find the effect of multi modal interventions including sensory stimulations and movement therapy among the stable preterm infants admitted to NICU/ward.

Type of Research Intervention: Randomized Clinical Trial.

Selection of Participants: Medically stable preterm infants born between 28 and 36 week of gestation with the Birth weight ranging from 1,000–1500 g.

Voluntary Participation: You do not have to agree that your infant can be studied by us. You can choose to say no and any services that you and your family receive at this centre will not change. We know that the decision can be difficult when it involves your PN. You can ask as many questions as you like and we take the time to answer them. You don't have to decide today. You can think about it and tell me what you decide later.

Procedure: The preterm Neonate (PN) is first assessed for their physiological status and neuromotar maturation by using Infant Neurological International Battery (INFANIB). Then they were allocated in one of the two groups randomly. One group (experimental group) is given with the multi modal stimulations including both sensory (auditory, touch, visual and vestibular) and movement therapy (passive movements of all the joints and antigravity movements in prone and supported sitting) along with the routine medical and nursing management. And second group (control group) is receiving only the routine medical and nursing management.

Duration: Total of one week intervention where the multimodal stimulations were applied for 25-30 minutes per day for five days.

Risks and Discomforts: Although the interventions and the assessment procedure has been proved to be safe for high risk neonates but the chances of any is unavoidable complications can't be ignored. Thus the physiological parameters of PN is kept on observation throughout the assessment and treatment period. If the physiological/ behavioral stress is reported, intervention was modified (particular stimulation paused for 15 s and resumed if parameters recovered).

Benefits: The PN participating in the control group will not have any direct benefits, but the scores of INFANIB may predict the developmental status of the PN. Whereas the PN of experimental group may get benefit from the interventions and their neuromotor development can be enhanced.

Reimbursements: Your daughter/son will not be provided with any payment to take part in the research.

Confidentiality and Sharing of Research Findings: The information about your infant will not be shared outside of the research team and will be kept confidential. The collected data, still photographs and video-tapings will be used for theses presentations in scientific conferences or publishing in the scientific journal only after masking the identity of your PN.

Right to refuse or withdraw: You may choose not to have your PN participate in this study. Choosing to participate or not will not affect either your own or your PN's future treatment at the Centre here in any way. You and your infant will still have all the benefits that would otherwise be available at this Centre.

Contact details:

Dr. Vencita Priyanka Aranha
Pediatric Physiotherapist, MMIPR
Mob: 8607274555
Email: vencita.peds@mmumullana.org

PART II: Certificate of Consent

I have been asked to give consent for my preterm Neonate (PN) to participate in this research study which will involve multi-modal stimulations to promote the neuromotor behaviour among the PN. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my PN to participate as a participant in this study.

Name of Parent or Guardian _____

Signature of Parent of Guardian_____

Date _____

Day/month/year

If illiterate:
(A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.)

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant

Name of Researcher/person taking the consent: **VENCITA PRIYANKA ARANHA**

Annexure-II: Informed Consent Form (Hindi)

जानकारी एवं अनुमति पत्र

अनुसंधान का विषय : अस्पताल में भर्ती अपरिपक्व नवजात शिशुओं के न्यूरो- मोटार विकास में बहुविध उत्तेजना का प्रभाव

मुख्य अनुसंधानकर्ता : वेंसिटा प्रियंका अरन्हा

मार्गदशक : डॉ० अक्ष चाहाल (प्रपि. एच. डि)

अनुसंधान का प्रकार : यद्वन्छिक तनयंत्रित

प्रतिभागियों का चयन : नवजात शिशुओं का गहन चिकित्सा विभाग I महर्षि मार्कंडेश्वर अस्पताल मुलाना-हरियाना।

प्रकिया:- चिकित्साकीय रूप स्थिर सभी अपरिपक्व नवजात शिशुओं का पहले दिन का मूलयांकन को इन्फानिब (INFANIB) के मदद से किया जाएगा । प्रयोगात्मक सामूह को एक सप्ताह (पाच दिन) 25 मिनट के एक दिन के लिए, एक दिन में एक बार 25 मिनट के लिए, मुख अनुसंधानकर्ता (डॉ० वेन्सिटा) के द्वारा चिकित्सा दिया जाएगा । बहुपविध चिकित्सा में सवेदी उत्तेजना (स्पर्श उत्तेजना, दृश्य उत्तेजना , श्रवन उत्तेजना, कर्ण कोटर उत्तेजना) 15 मिनट के लिए , और गति चिकित्सा (निस्रिय गति, गुरुत्वाकर्षण विरोधी गति) 10 मिनट के लिए किया जाएगा ।

जोखिम और सावधातनयां: हालांकि यह हत्सक्षेप और मूलयांकन प्रकिया अपरिपक्व नवजात शिशुओं के लिए सुरक्षित साबत हो चुका हैं , लेकिन इस में हृदय गति, त्वचा, तापमान और शारीररक मापदंड के वृद्धि की संभावना है। इन मानकों की सुरक्षित सीमा को बनाऐ रखने के लिए सावधातनयां ली जाएगी ।

लाभ - प्रयोगात्मक सामूह में नवजात शिशुओं के हत्सक्षेप से लाभ हो सकता हैं और उनके सकल न्यूरो- मोटार विकास को बढाया जा सकिा हैं। तनयंत्रण सामूह में नवजात शिशुओं को कोई भी प्रत्यक्ष लाभ नहीं होगा लेकिन इन्फानिव के अंक से नवजात शिशु के विकास की स्थिति अपेक्षित होगी ।

गोपनीयता: शिशुओं से एकत्र आकंङो को सम्मेलनों में निबंध के रूप में या पत्रिकाओ में प्रकाशित के लिए इस्तमाल किया जाएगा। हलंकी शिशु का नाम, वीडियो रिकॉर्डिंग केवल उिनकी पहचान छुपाने के बाद प्रकाशित की जाएगी।

निकलने/ इनकार करने का अधिकार: शिशु की भागीदारी मा- बाप स्वैन्छिक होगीऔर वे मना कर सकते हैं या अध्ययन से वे पीछे हट सकते हैं ।

संपर्क:- डॉ० वेंसिटा प्रियंका अरन्हा

बाल चिकित्सा फिजियोथेरेपिस्ट

महर्षि मार्कंडेश्वर अस्पताल, मुलाना-हरियाना।

मोबाईल :- 8607274555

ई-मेल:- vencita.peds@mmumullana.org

अनुमति पत्र

शिशु का नाम :-

माता/ पिता का नाम :-

तिथि :-

हम समझते हैं कि हमारे शिशु को आंकलन प्रक्रिया और एक हफ्ते के लिए कुछ इलाज़ के उपायों से गुजरना होगा। हम समझते हैं कि उपचार के दौरान शारीररि मापदूंड में कुछ बदलाव हो सकता हैं। अनुसंधानकर्ता ने आक्ष्वसन दिया है कि, सभी आवश्यक सुरक्षा सावधातनयों को किया जाएगा।

हम समझते हैं कि, हमारे शिशु कौी भागीदारी से उसे/ हमें कोई प्रत्यक्ष लाभ नही हो सकता हैं। किन इसका उद् हमारे शिशु कि समग्र विकास होगा। हम समझते हैं कि, हमारे शिशु की, तस्वीर या विडियो रेकारिॉर्डिंग, एकत्र आकंडो को सम्मेलन में प्रबूंध प्रस्तुति के रूप में या पत्रिकाओं में प्रकाशन के लए इस्तामाल किया जाएगा। हाला कि शिशु का नाम। परिचय, तस्वीर या विडियो रेकारिॉर्डिंग केवल उनकी पहचान छुपाने के बाद ही प्रकाशित की जाएगी। मुझे यह भी बतया गया कि मेंरे शिशु की भागीदारी स्वैच्छिक है, और में कभी भी मना कर सकते हैं या अध्ययन से पीछे हटा सकते हैं।

हम इस बात की पुष्टि करते हैं कि, वेंसिटा प्रियंका अरन्हा ने हमे, हमारे शिशु की अनुसंधान, प्रक्रिया, संभापवित जोखिम और लाभ के बारे में बाता दिया हैं। हम इस सहमति पत्र को पढ़कर समझ चुके हैं। इस लए हमअपने शिशु को इस शोध में भाग लेने केलिए सहमत हैं।

माता/ पिता का हस्ताक्षर। अनुसंधानकर्ता का हस्ताक्षर

Annexure III: Data collection sheet

Pre and Post Outcomes Following Physiotherapy Interventions for Preterm Infants

(PIPI-O)

Demographic Information		Birth Parameters	
Baby Name	:	Birth weight	:
Gender	:	Birth Length	:
Gestational Age	:	OFC	:
Date of Birth	:	APGAR score	:
		GPL	:

Out comes	Pre intervention	Intervention					Post Intervention
		D1	D2	D3	D4	D5	
Weight (Grams)							
Length (Centimetres)							
OFC (Centimetres)							
Heart rate (Beats/minutes)							
Respiratory rate (Breaths/minutes)							
SPO_2							
Body Temperature (°Celsius)							
State related behaviour							
Pain (NIPS)							
INFANIB							
Serum Calcium							

Neonatal Infant Pain Scale (NIPS)

Parameters	0 point	1 point	2 point
Facial expression	Relaxed	Grimace	-
Cry	No cry	Whimper	Vigorous crying
Breathing pattern	Relaxed	Change in breathing	-
Arms	Relaxed	Flexed/extended	-
Legs	Relaxed	Flexed/extended	-
State of Arousal	Sleeping/ Awake	Fussy	-

Pain level: 0–2 points = No pain, 3–4 points = Moderate pain, >4 points = Severe pain

State Related Behaviours

States	
Sleeping	**1A**
	1B
	2A
	2B
Transitional	**3A**
	3B
Awake	**4AL**
	4AH
	4B
Active	**5A**
	5B
Crying	**6A**
	6B

INFANIB

Date of Exam _____

NAME _____ CIRCLE ONE Corrected Gestational Age _____

ITEM	START SCORE	MAJOR CHANGE									
1	Birth		**SUPINE** Hands closed/open		Closed		Sometimes Closed		Open		
2	Birth		Scarf sign	Less Than #1	0° to 15° 1	15° to 45° 2	45° to 60° 3	60° to 80° 4		Past #4	
3	Birth		Heel to ear	Over 100°	90° to 180°	60° to 90°	40° to 60°	10° to 40°		Under 10°	
4	Birth		Popliteal angle	Under 80°	80° to 90°	90° to 110°	110° to 150°	150° to 170°		Over 170°	
5	Birth		Leg abduction	Under 40°	40° to 70°	70° to 100°	100° to 130°	130° to 150°		Over 150°	
6	Birth		Dorsiflexion of foot	0° to 10° Foot Leg	10° to 40° Foot Leg	40° to 70° Foot Leg	70° to 80° Foot Leg	80° to 90° Foot Leg			
7	Birth	9 mos.	Foot grasp		No Grasp		Barely Grasp		Grasp		
8	Birth	6 mos.	Tonic labyrinthine supine		Absent		Shoulder retraction or some extension of trunk or legs		Shoulder retraction and full leg extension		
9	Birth	6 mos.	Asymmetric tonic neck reflex		Absent		Postures in, can move out		Persistent		
10	Birth		Pull to sitting		Head extended Arms extended		Head up Arms ext.	Head flexed Arms ext.	Head flexed Arms flexed		
11	4 mos.		Body derotative		Present to both sides		Slow or mildly asymmetrical		Absent or markedly asymmetrical		
12	9 mos		Body rotative		Present		Poor		Absent		
13	Birth		**PRONE** All fours	Lifts Head	Head up 45°	Forearms only	Head up 90°	Bears weight on extended arms	Assumes all fours unsteadily	Assumes all fours well	Stands up through Plantigrade
14	Birth	9 mos.	Tonic labyrinthine prone		Absent		With Head Flexion: Shoulder protraction or some flexion of legs		With Head Flexion: Shoulder protraction and arms, hips, or legs under trunk		
15	Birth		**SITTING** Sitting position				L3		L5		
16	6 mos.		Sideways parachute		Present in both arms		Slow or mildly asymmetrical		Absent or markedly asymmetrical		
17	9 mos.		Backwards parachute		Present in both arms		Slow or mildly asymmetrical		Absent or markedly asymmetrical		
18	Birth		**STANDING** Weight bearing	Primitive reflex	No weight bearing		Poor weight bearing Breaks at knees	Unequal weight bearing			
19	3 mos.		Positive support reaction		Feet flat		5 to 30 sec. on toes then drop to feet flat		> 30 sec. on toes		
20	7 mos.		**SUSPENDED** Forward parachute		Present		Slow or mildly asymmetrical		Absent or markedly asymmetrical		
										FACTOR SCORES	
										TOTAL SCORE	